

REMARKS

**A. Regarding the Amendments**

In accordance with the present invention, there are provided methods for treating mitochondrial disorders comprising administering to a subject in need thereof an effective amount of a pyrimidine-based nucleoside. Invention methods are particularly effective in treating conditions in which there is a decrease in pyrimidine biosynthesis. Accordingly, invention methods are useful for treating a variety of pathological conditions, such as, for example, mitochondrial encephalomyopathy with lactic acidemia and stroke-like episodes (MELAS), and the like.

By the present request, claims 28-65 have been added to define Applicant's invention with greater particularity and not in response to any properly cited reference. As amended, the claims are supported by the specification and the original claims and add no new matter. Thus, upon entry of the amendments, claims 1-65 will be pending.

**B. Request for Interference**

By the present communication, Applicant respectfully requests declaration of an interference action under 37 C.F.R §1.604. In accordance with this request, Applicant seeks to have an interference declared as to the claimed subject matter of the application presently at issue with regard to the claimed subject matter of published U.S. Application Serial Nos. 09/930,494 filed August 16, 2001 and published April 25, 2002, 09/838,136 filed April 20, 2001 and published August 23, 2001 and 09/144,096 filed August 31, 1998 and published June 28, 2001. It is requested that an interference be declared between the present application and the three above-referenced applications, as published.

Under 37 C.F.R. § 1604, an applicant may request an interference with the application of another. In order to do so, the applicant must suggest a proposed count and identify at least one claim of the applicant's invention that corresponds to the count, identify the other application and claims that correspond to the count, if known, and explain why an interference should be

declared. Applicant respectfully submits that in light of the following statements, an interference should be declared.

Applicant proposes the following count and the claims of the present application and Application Nos. 09/930,494, 09/838,136 and 09/144,096 that correspond with this count:

A method for treating or preventing pathophysiological consequences of mitochondrial respiratory chain dysfunction in a mammal comprising administering to said mammal in need of such treatment or prevention an effective amount of a pyrimidine nucleotide or a pyrimidine nucleotide precursor.

Claim 29 of the subject application is identical to claim 1 of U.S. Application Serial No. 09/930,494 and both correspond substantially to the count. Dependent claims 30-43 further define the subject matter of claim 29 and are identical to claims 2, 6-10, 18, 21-26, 32, 37, 39 and 41 of U.S. Application Serial No. 09/930,494. Additionally, claim 47 of the subject application is identical to claim 1 of U.S. Application Serial No. 09/838,136 and claim 1 of U.S. Application Serial No. 09/144,096, and all three correspond substantially to the count. Dependent claims 48-62 further define the subject matter of claim 47 and are identical to claims 2, 6-11, 18, 20-25, 31, 36, 38 and 40 of U.S. Application Serial No. 09/838,136 and to claims 2, 6-11, 18, 20-25, 31, 36, 38 and 40 of U.S. Application Serial No. 09/144,096.

Additionally, it is noted that claims 44-46 of the subject application are identical to claims 37, 39 and 41 of U.S. Application Serial No. 09/930,494.

Further, claims 63-65 of the subject application are identical to claims 36, 38 and 40 of U.S. Application Serial No. 09/838,136, and identical to claims 36, 38 and 40 of U.S. Application Serial No. 09/144,096.

It is respectfully submitted that the specification of the present application supports addition of new claims 29-65. Claims 29 and 47 are supported, for example, by the language on page 4, lines 19-21, which states, "[t]he present invention provides methods for the treatment of mitochondrial disorders by administering one or more of a pyrimidine-based nucleoside, a precursor thereof, or the like." Claims 30 and 48 are supported, for example, by original claim 6.

Claims 31-35 and 49-53 are supported, for example by page 7, lines 12-14. Claims 36 and 55 are supported, for example, at page 10, line 21 to page 11, line 8. Claims 37, 38, 44-46, 56, 57 and 63-65 are supported, for example by the list on page 7, lines 1-29. Claims 39 and 58 are supported in the specification at, for example, page 7, line 30 to page 8, line 12. Claims 40-42 and 59-61 are supported, for example, at page 8, lines 1-3 and in originally filed claim 7. Claims 43 and 62 are supported, for example, by the text at page 8, lines 23-29. Finally, new claim 54 is supported, for example at page 5, line 1 to page 6, line 9.

It is alleged by the Applicant that the subject matter of Application Nos. 09/930,494, 09/838,136 and 09/144,096 is drawn to the same patentable invention as the claimed invention and that Applicant was first to invent the patentable invention.

The Examiner's attention is respectfully drawn to the enclosed declaration of Dr. Naviaux, the inventor of the claimed invention, stating that he believes he was the first to invent the use of pyrimidines for treating mitochondrial diseases. In his declaration, Dr. Naviaux states that he conceived of the subject matter of the claimed inventions on or about June 30, 1995. Dr. Naviaux further states that he was diligent in reducing his invention to practice by the performance of clinical trials on patients CMZ, KL, SF and CS beginning with the trial on CMZ on or about July 15, 1996. Dr. Naviaux's diligence continued with the clinical trials on KL, SF and CS and a constructive reduction to practice by the filing of U.S. Provisional Application No. 60/121,588, filed February 23, 1999 and PCT application no. US00/04663 on February 23, 2000, which claimed priority to the provisional application. The present application is a U.S. National Stage application of the PCT application.

In light of the above, it is respectfully submitted that an interference should be declared between the present application and U.S. Application Serial Nos. 09/930,494, 09/838,136 and 09/144,096, as the applications are directed to the same subject matter, in order to determine who is the first inventor. As set forth in the enclosed declaration, Applicant asserts that he was the first to invent the technology at issue. Therefore, as the prior inventor, Applicant's application should be allowed to remain pending and the claims of U.S. Application Serial Nos. 09/930,494,

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Application Serial No.: 09/889,251  
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09/838,136 and 09/144,096 should be declared invalid as anticipated under 35 U.S.C. §102(g). An interference is proper among these 4 applications, as the applications contain claims to the same patentable invention. As Dr. Naviaux was the first to conceive of the invention and was diligent from conception to reduction to practice, declaration of Dr. Naviaux as the first to invent is respectfully requested.

By the present submission, Applicant hereby requests that an interference be declared between the present application and U.S. Application Serial Nos. 09/930,494, 09/838,136 and 09/144,096.

#### CONCLUSION

In view of the above amendments and remarks, declaration of an interference between the present application and U.S. Application Serial Nos. 09/930,494, 09/838,136 and 09/144,096 under 37 C.F.R. §1.604 is respectfully requested.

If the Examiner would like to discuss any of the issues raised in the Request for Interference under 37 C.F.R § 1.604, Applicant's representative can be reached at (858) 677-1456. Please charge additional claim fees, or make any credits, to Deposit Account No. 50-1355.

Respectfully submitted,

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